



Timothy Murbach, ND, DABT
AIBMR Life Sciences, Inc.
1425 Broadway, Suite 458
Seattle, WA 98122

Re: GRAS Notice No. GRN 001101

Dear Dr. Murbach:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Triton Algae Innovations (Triton) to cease our evaluation of GRN 001101, which we filed on March 7, 2023. We received this request on August 31, 2023.

The subject of the notice is a dried biomass of *Chlamydomonas reinhardtii* strain “TAI114” (*C. reinhardtii* “TAI114”) for use as a flavoring agent, adjuvant, and nutritive ingredient in meat, seafood, and fish alternatives at levels up to 0.7% w/w in the meat, seafood, or fish alternative fraction of the finished food.¹ The notice informs us of Triton’s view that these uses of dried biomass of *C. reinhardtii* “TAI114” are GRAS through scientific procedures.

On May 16, 2023 and June 23, 2023, we informed you that we could not continue our evaluation due to the toxicology deficiencies identified in the notice. Specifically, we noted that there was not sufficient data presented on the dietary exposure to the protoporphyrin IX that is present in the ingredient to support the safety conclusion made by Triton. Given the substantive nature of this issue, we recommended that Triton request that we cease our evaluation of the notice. We also suggested that Triton request a pre-submission meeting with us prior to submitting a revised GRAS notice for evaluation without prejudice.

¹ Triton states that dried *C. reinhardtii* “TAI114” is not intended for use in infant formula, products under the jurisdiction of the U.S. Department of Agriculture, and in foods for which standards of identity preclude such use.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001101 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan J.
Carlson -S
Date: 2023.09.01 14:06:27
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition